

REMARKS

In accordance with the foregoing, claims 1-36 are pending and under consideration.

On August 24, 2004, Examiners Chorbaji and Jastrzab kindly granted the undersigned a personal interview to discuss the application. The Examiners' time in preparing for and conducting the interview is acknowledged and gratefully appreciated.

During the interview, there was a discussion regarding where the application provides antecedent basis for the limitation "without a ported nozzle." This discussion related to items 1-4 of the Office Action. In the Background of the Invention, page 4, lines 1-5 of the application, as filed, provides:

Together these form all sides of the housing within a sterilization-sealing station, a ported nozzle is positioned between the top and bottom webs for selective movement of gases into and out of the housing. Upon the evacuation of at least some of the air from the housing via the ported nozzle, steam is introduced into the housing through the ported nozzle.

This portion of the application indicates that a ported nozzle was used to inject gas.

The paragraph bridging pages 4 and 5 of the application provides:

While the form, fill and seal process has advantages over the chamber sterilization process, there is room for improvement. In the form, fill and seal process, steam is injected onto a cold article through a nozzle. The steam may condense on the article, thereby causing water spots when dried. If the steam condensation is large enough, the package can fill up with water. The nozzle significantly increases the cost of the form, fill and seal equipment.

This paragraph indicates that the ported nozzle caused problems.

In the Detailed Description of the Preferred Embodiments, page 15, lines 6-8 provides:

For the purpose of gas injection, pins 600 are provided within the side walls 425 of seal die 424. The side walls 425 located to the front, back, left and right of the sterilization-sealing station 410 are shown in various drawings.

When read, in view of the drawings, this portion of the application indicates that the inventor proposes to use pins 600, not a ported nozzle, to inject gas.

In view of the foregoing, it is submitted that the application provides clear antecedent basis for "without a ported nozzle." Accordingly, it is submitted that the rejections raised in items 1-4 should be withdrawn.

During the interview, there was also a discussion regarding why U.S. Patent No.

5,749,203 to McGowan, Jr. teaches away from a pretreatment area. In the Background of the Invention, column 1, lines 36-45 of the '203 patent provides:

*The purpose of the preconditioning phase is to elevate the temperature and relative humidity of the palletized articles. At these elevated temperatures, ethylene oxide gas is **thought** to be more molecularly active and therefore performs more effectively as a sterilizing agent. Additionally, in the presence of higher relative humidity levels, ethylene oxide is thought to flow more freely through packaging compositions and materials used in forming the articles which are undergoing sterilization (emphasis added).*

This portion of the reference indicates that a preconditioning phase was used based on a once-had belief that ethylene oxide gas performs better at elevated temperatures.

The paragraph bridging columns 2 and 3 of the '203 provides (with emphasis added):

While the above described process[es] are effective for sterilizing surgical articles, both processes have several drawbacks. One such drawback is the length of time required for each of these processes. Another drawback is the concentration of ethylene oxide used during the sterilization phases. At these concentrations of ethylene oxide, generally from between about 400 mg/l to about 1500 mg/l, safety concerns stemming from both toxicity as well as flammability issues are ever present.

This portion of the reference indicates that the processes described in the Background of the Invention are problematic because they require too much time.

Column 1, lines 26-28 of the '203 patent describe the phases of the chamber sterilization process as follows:

Traditionally, the chamber sterilization process includes four phases: (i) preconditioning, (ii) sterilization (iii) degassing, and (iv) quarantining.

Column 3, lines 17 through column 4, line 28 of the '203 patent describes how time is saved. With this process, "a sterilizing gas is introduced . . . into the housing", "the closed housing is then conveyed to a degassing area," and "upon degassing, the housing is conveyed to a quarantine area." See column 3, lines 55 and 56 and column 4, lines 17, 22 and 23. Of the five phases described at column 1, lines 26-28, pre conditioning is missing. The '203 patent teaches away from preconditioning.

The inventor recognized that there are drawbacks associated with the '203 patent. The inventor realized that there may be some truth in the once-had belief that ethylene oxide gas is more active at elevated temperatures. The inventor therefore proposed to use preconditioning. Perhaps the Examiner believes that using preconditioning is an insufficient inventive step.

However, the '203 patent in no way teaches to use preconditioning. Only the present application teaches to use preconditioning. Any belief that preconditioning is suggested by the '203 patent is hindsight, relying upon what was learned from reading the present application.

Independent claims 1 and 15 refer to pretreatment. Any rejection of these claims relying on the '203 patent for pretreatment should be withdrawn.

Independent claims 8 and 12 refer to gas injection pins to inject gas. The Examiner relies upon the Multivac Packaging Machine reference for this limitation. Initially, it should be noted that the Multivac Packaging Machine reference was provided to the Examiner with annotations made by the inventor and others. These annotations are not part of the reference.

There are numerous differences between the system proposed in the reference and that proposed by the inventor. The Examiner asserts that it would have been obvious to use the Multivac pins in the '203 patent "in order to establish a uniformity of gas distribution." The Examiner is referring to an advantage stated in the Multivac reference on page 1, column 1. This advantage is "Since pins are located on both sides of [the] die, uniformity of gas distribution is easy to obtain." The advantage describes the difference between using pins on one side of a die versus using pins on both sides of a die. Perhaps this advantage renders obvious having pins on both sides of a die if they were previously present on only one side of a die. However, this advantage in no way renders obvious using gas injection pins in the '203 patent (where they were not present before).

As the title indicates, the Multivac gas injection pins are used for gas flushing. Gas flushing is when one gas is replaced with another gas. For example, if a bag contained food and air, the pins could be used to inject carbon dioxide into the bag until a substantial portion of the air were displaced. In this manner, the color and taste of the food may be preserved.

On the other hand, gas displacement is not necessary in the '203 patent. Column 9, lines 32-37 of the '203 patent describes that the chamber is evacuated. Oxygen is removed from the chamber without a gas flushing process. Column 10, lines 1-46 of the '203 patent describes how the evacuation is performed. Referring to Fig. 4B, after a lid 418 and a seal die 424 are secured together, three chambers are formed. These chambers are represented with the letters A, B and C in Fig. 4B. The chambers A and C are evacuated respectively through ports 420 and 428. Chamber B is evacuated through port 448 in nozzle 446. With the evacuation, there is substantially no need for gas displacement, flushing, as proposed by the Multivac reference.

Page 3, column 1 of the Multivac reference describes typical applications as packaging for red meats, sausage, pork, poultry, fish, cheese, bakery products and fruits and vegetables. On the other hand, the '203 patent is directed to a very different application, namely sterilization of medical articles.

It appears that the Examiner is using prohibitive hindsight in making the rejection. As mentioned above, the '203 patent discloses a nozzle 446 and a port 448. Is the Examiner proposing that it would have been obvious to use the Multivac pins in addition to the nozzle 446? Alternatively, does the Examiner propose to use the pins instead of the nozzle 446? If the Examiner proposes to eliminate the nozzle 446, where is the motivation for doing this. The present invention, not the prior art, suggests using pins instead of a nozzle. There is no motivation to make the changes suggested by the Examiner. Accordingly, the obviousness rejection should be withdrawn.

Independent claims 8 and 22 relate to gas injection pins. Any rejection of these claims, relying upon the Multivac reference for the gas injection pins, should be withdrawn.

Independent claim 33 recites that gas injection is performed without a ported nozzle. Claim 33 is rejected as being obvious over McGowan, Jr. in view of the Multivac reference. However, "without a ported nozzle" is not even mentioned in the rejection. Nowhere does the Multivac reference teach that a ported nozzle should not be used. Perhaps the Examiner is confused in this matter. Only the application teaches that a ported nozzle should not be used. Claim 33 patentably distinguishes over any proper combination of the '203 patent and the Multivac reference.

There being no further outstanding objections or rejections, it is submitted that the application is in condition for allowance, except for possible provisional obviousness type double patenting rejections. An early action indicating allowable subject matter is respectfully requested.

If there are any formal matters remaining after this response, the Examiner is requested to telephone the undersigned to attend to these matters.

If there are any additional fees associated with filing of this Amendment, please charge the same to our Deposit Account No. 19-3935.

Respectfully submitted,

STAAS & HALSEY LLP

Date: Sept. 30 2004

By: Mark J. Henry
Mark J. Henry
Registration No. 36,162

1201 New York Avenue, NW, Suite 700
Washington, D.C. 20005
Telephone: (202) 434-1500
Facsimile: (202) 434-1501